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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,254	01/04/2002	Jeffrey H. Burbank	T4342-14516US01	6185
181 7590 04/16/2010 MILES & STOCKBRIDGE PC 1751 PINNACLE DRIVE SUITE 500 MCLEAN, VA 22102-3833				
EXAMINER ASTORINO, MICHAEL C				
ART UNIT 3769		PAPER NUMBER		
NOTIFICATION DATE 04/16/2010		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/037,254

Applicant(s)

BURBANK ET AL.

Examiner

Michael C. Astorino

Art Unit

3769

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 04, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-13, 19, 20, 25-27, 32, 33, 42-51 and 54-61 is/are pending in the application.
- 4a) Of the above claim(s) 52 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-13, 19, 20, 25-27, 32, 33, 42-51 and 54-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-646)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Examiner acknowledges the response filed May 04, 2009, wherein claims 1-6, 9-13, 19-20, 25-27, 32-33, and 42-61 are pending.

Election/Restrictions

Claim 52 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 4, 2009.

Claim Objections

Claim 53 is objected to because claim 53 is dependent on cancelled claim 22. It is possible Applicant had a typographical error in claim 53, and that claim 22 was meant to be claim 52. If so, claim 53 is withdrawn because claim 53 is dependent on a withdrawn claim 52. The examiner's best guess is that claim 53 is dependent on claim 52, as such claim 53 is withdrawn.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **40 (in figure 1A)**. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any

amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6, 9-13, 19-20, 25-27, 32-33, 42-51, and 54-61 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Process Claims

In particular, claims 1, 19, 25, 49, 50, and 51 are drawn to a process. Under 35 U.S.C. §101 a process must 1) be tied to a particular machine or apparatus or 2) transform underlying subject matter such as an article to a different state or thing. The claims include the following steps:

Claim 1 includes detecting a leak, deriving a signal, and generating an alarm;

Claim 19 includes combining detector signals, and generating an alarm signal;

Claim 25 includes combining detector signals;

Claim 49 includes detecting a leak, deriving a composite signal, and generating an alarm signal;

Claim 50 includes detecting a leak, deriving a composite signal, and generating an alarm signal; and

Claim 51 includes detecting signals from first and second sensors, and combining the signals.

In claims 1, 19, 25, 49, and 50 no particular machine is required and the method does not transform any particular article. In claim 51, first and second sensors are used, and sensors are a machine. However the machine, i.e. the sensors, do not impose a meaningful limit on the claim's scope and the use of the machine (i.e. sensors) is insignificant pre-solution activity.

Product Claims

In particular, claims 9, 13, 42, and 54 are drawn to a product. Under 35 U.S.C. §101 a product is non-statutory subject matter when a claim as a whole is not directed to a practical application of a law of nature, natural phenomenon, or abstract idea.

Claim 9 includes a first and second detector and a signal combiner;

Claim 13 includes a first and second detector and a signal combiner;

Claim 42 includes a signal filter; and

Claim 54 includes a signal filter.

In claims 9, 13, 42, and 54, the signal combiner and signal filter when read in light of the specification are directed to algorithms. Figures 6 and 8 are specifically directed to algorithms, "FIG. 6 is a flow chart indicating an alarm status upgrade *algorithm* according to an embodiment of the invention" and "FIG. 8 is a flow chart indicating an alarm status control algorithm which

may incorporate the status upgrade *algorithm* of FIG. 6.” (emphasis added). See also page 32 discussion of “simple analog system” and “signal multipliers”.

Claims 9, 13, 42, and 54 as a whole are directed to algorithms. Algorithms are abstract ideas, claims 42 and 54 as a whole are not directed to a practical application of an abstract idea and as such the claims are rejected. In claims 9 and 13, the heart of the claims are directed to a “signal combiner” and as a whole the claims are not directed to a practical application of an abstract idea and as such the claims are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-13, 19-20, 25-27, 32-33, 42-51, and 54-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Process Claims

In regards to device claims, the specification fails to describe so as to enable one of ordinary skill in the art to make or use of the algorithms for:

Claim 1, deriving a signal;

Claim 19, combining detector signals;

Claim 25, combining detector signals;
Claim 49, deriving a composite signal;
Claim 50, deriving a composite signal; and
Claim 51, combining the signals.

The Applicant has not disclosed in the specification the use of the algorithms to perform these steps. As such one of ordinary skill in the art would not know how to make or use the invention.

Product Claims

In regards to device claims, the specification fails to describe so as to enable one of ordinary skill in the art to make or use of a “signal filter” and “signal combiner”. The broadest interpretation of the phrases “signal filter” and “signal combiner” in light of the specification is an algorithm. The Applicant has not disclosed in the specification via computer code, flow chart, or otherwise the algorithm. As such one of ordinary skill in the art would not know how to make or use the invention.

The Applicant is invited to explain, to make the record clear, reasons that the rejection under 35 U.S.C. 112, first paragraph, does not apply.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9-13, 19-20, 25-27, 32-33, 42-51, and 54-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards the

method claims including: Claim 1, deriving a signal; Claim 19, combining detector signals; Claim 25, combining detector signals; Claim 49, deriving a composite signal; Claim 50, deriving a composite signal; and Claim 51, combining the signals; the examiner cannot discern the metes and bounds of these claimed method steps.

In regards to the product claims the broadest reasonable interpretation of “signal filter” and “signal combiner” are algorithms and algorithms lack structure. As such the examiner cannot discern the metes and bounds of these claimed elements. Additionally the broadest reasonable interpretation of claimed elements is such that the examiner has given these non-structural elements no patentable weight.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 9-13, 42-50, and 54-61 are rejected under 35 U.S.C. 102(e) as being anticipated by O’Mahony et al. US Patent Number 6,585,675 B1.

See previous office action and response to arguments section below. In regards to claims 9-13, 42-48, and 54-61, the broadest reasonable interpretation of “signal filter” and “signal

combiner” are algorithms and algorithms lack structure. As such the examiner has given these non-structural elements no patentable weight.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

In regards to claim 1, applicant argues O'Mahony does not detect a leak of blood flow from an extracorporeal blood circuit. However O'Mahony clearly states in the Summary of the Invention that, “[a] blood flow controller has been developed that controls blood flow through an *extracorporeal blood circuit*.” emphasis added. (See column 3, lines 31-33).

Applicant also argues that O'Mahony fails because of the citation to the withdrawal of pressure. However the rejection also included,

“The monitoring CPU 714 provides a safety check that independently monitors each of the critical signals, including [1] **signals indicative of blood leaks**, [2] pressures in blood circuit, [3] weight of filtrate bag, [4] motor currents, [5] **air in blood line detector** and [6] motor speed/position. The monitoring CPU has stored in its memory safety and alarm levels for various operating conditions of the ultrafiltrate system. By comparing these allowable preset levels to the real-time operating signals, the monitoring CPU can determine whether a safety alarm should be issued, and has the ability to independently stop both motors and reset the motor controller and controller CPU if necessary.” (emphasis added).

Applicant also uses signals indicative of blood leaks and air in a fluid circuit and presence of fluid as conditions for alarm detection see 1 and 5 above. As far as claim 2, the probability is 0% when the alarm is off and 100% when the alarm is on.

Regarding the device claims, O'Mahony is sufficient to reject the claims because the “signal filter” and “signal combiner” are algorithms and algorithms lack structure.

The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Astorino whose telephone number is (571)272-4723. The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael C. Astorino/
Primary Examiner, Art Unit 3769

April 11, 2010